PUBLIC HEALTH COUNCIL

Meeting of the Public Health Council, Tuesday, May 25, 1999, 10:00 A.M., Massachusetts Department of Public Health, 250 Washington Street, Floor 2, Boston, Massachusetts. Present were: Dr. Howard K. Koh (Chairman), Dr. Clifford Askinazi, Mr. Manthala George Jr., Mr. James Phelps, Mr. Albert Sherman, Ms. Janet Slemenda, Mr. Joseph Sneider, and Dr. Thomas Sterne. Mr. Bertram Yaffe absent. Also in attendance was Ms. Donna Levin, General Counsel.

****

Chairman Koh announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance, in accordance with the Massachusetts General Laws, Chapter 30A, Section 11A 1/2.

****

The following members of the staff appeared before the Council to discuss and advise on matters pertaining to their particular interests: Dr Deborah Klein-Walker, Assistant Commissioner, Bureau of Family and Community Health; Ms. Janet Farrell, Acting Director, Universal Newborn Hearing Screening Program; Dr. Paul Dreyer, Director, Ms. Jean Pontikas, Assistant Director, Ms. Nancy Murphy, Policy Analyst, Division of Health Care Quality; Ms. Nancy Ridley, Assistant Commissioner, Bureau of Health Quality Management; Mr. Robert Hallisey, Director, Division of Radiation Control, Ms. Joyce James, Director, Determination of Need Program; and Attorneys Howard Saxner and Carl Rosenfield, Deputy General Counsels, Office of the General Counsel.

RECORDS OF THE PUBLIC HEALTH COUNCIL MEETING OF FEBRUARY 23, 1999:

Records of the Public Health Council meeting of February 23, 1999 were presented to the Council. After consideration, upon motion made and duly seconded, it was voted (unanimously): That, records of the Public Health Council Meeting of February 23, 1999, copies of which had been sent to the Council Members for their prior consideration, be approved, in accordance with Massachusetts General Laws, Chapter 30A, Section 11A 1/2.

PERSONNEL ACTIONS:

In a letter dated May 13, 1999, Blake Molleur, Executive Director, Western Massachusetts Hospital, recommended approval of the appointment to the consultant medical staff of Western Massachusetts Hospital, Westfield. Supporting documentation of the appointee's qualifications accompanied the recommendation. After consideration of the appointee's qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Executive Director of Western Massachusetts Hospital, under the

authority of the Massachusetts General Laws, Chapter 17, Section 6 the following appointment to the consultant medical staff of Western Massachusetts Hospital be approved:

APPOINTMENT	**RESPONSIBILITY**	**MEDICAL LICENSE NO.**
Mary Gina Ratchford, M.D.	Ophthalmology	80945

In a letter dated May 10, 1999, Robert D. Wakefield, Jr., Executive Director, Lemuel Shattuck Hospital, recommended approval of the reappointments to the medical and allied health staffs of Lemuel Shattuck Hospital, Jamaica Plain. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees'qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Executive Director of Lemuel Shattuck Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the following reappointments to the medical and allied staffs of Lemuel Shattuck Hospital be approved:

REAPPOINTMENTS	**STATUS/SPECIALTY**	**MEDICAL LICENSE NO.**
physicians		
St. John Donnie McGrath, M.D.	Active/Internal Medicine	78054
Carl Fulwiler, M.D.	Active/Psychiatry	80208
Ronald Nasif, M.D.	Consultant/Orthopedics	46262
George Whitelaw, M.D.	Active/Orthopedics	34608
allied health professionals		
Phyllis Bluhm, PA-C		259
Omega Bradley, PA-C		382
Ellena Diggins, PA-C		333
Beth Ferguson, PA-C		62
Janet Guilfoyle, PA-C		593
Rebecca Heaton, PA-C		334
Katherine E. Keefe, PA-C		228
Marcia Sommer-Winfrey, PA-C		198
Virgina McCullough, PA-C		512
Ruth Haskal, RNP		108448
Mark McKee, RNP		154665

In letters dated May 6, 1999, Katherine Domoto, M.D., Associate Executive Director for Medicine, Tewksbury Hospital, Tewksbury, recommended approval of the appointment/reappointments of physicians to the active, affiliate and consultant medical staffs of Tewksbury Hospital. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees' qualifications, upon motion made

and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Associate Executive Director for Medicine of Tewksbury Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the following appointment/reappointments to the active, affiliate, and consultant medical staffs of Tewksbury Hospital be approved for a period of two years beginning May 1, 1999 to May 1, 2001:

APPOINTMENTS	**STATUS/SPECIALTY**	**MEDICAL LICENSE NO.**
Gauri Bhide, M.D.	Provisional Consultant/ Hematology Oncology	76591
REAPPOINTMENTS		
Jesus Flores, M.D.	Active/Internal Medicine	41509
Murat Anamur, M.D.	Consultant/ Hematology Oncology	72107
Michael McGee, M.D.	Affiliate/Psychiatry	56459
Michael Popik, M.D.	Consultant/Radiology	52454

PROPOSED REGULATIONS:

INFORMATIONAL BRIEFING ON PROPOSED LICENSURE REGULATIONS FOR UNIVERSAL NEWBORN SCREENING AND RELATED AMENDMENTS TO THE HOSPITAL LICENSURE REGULATIONS (105 CMR 130.000) AND BIRTH CENTER LICENSURE REGULATIONS (105 CMR 142.000):

Dr. Deborah Klein-Walker, Assistant Commissioner, Bureau of Family and Community Health, accompanied by Ms. Janet Farrell, Acting Director, Universal Newborn Hearing Screening Program and Dr. Paul Dreyer, Director, Division of Health Care Quality presented the informational briefing on the proposed regulations in regards to universal newborn screening and related hospital licensure amendments. The following information was provided:

- An Act Providing for Hearing Screening of Newborns was signed into law in Massachusetts in the 1998 legislative session (Chapter 243 of the Acts of 1998). The Department of Public Health was required to promulgate regulations to implement the law. Since that time, the Department has been working with a multi-disciplinary advisory committee to develop amendments to hospital and birth center licensure regulations regarding universal newborn screening programs.

- The Universal Newborn Hearing Screening Law, as the Massachusetts statute is known, mandates that a hearing screening be performed on all newborns in the Commonwealth of Massachusetts prior to discharge from the hospital (with the sole exception that parents or guardians of the newborn infant may object based on sincerely held religious belief). The law further mandates that the cost of the universal newborn hearing screen be covered by health insurance plans and that the Commonwealth serve as payer of last resort for families

who are uninsured or whose insurance is not subject to state mandate.

- Under the proposed regulations, hospitals will be responsible for providing information to families prior to the hearing screen, explaining the importance of newborn hearing screening and early intervention for children identified with hearing loss. Each hospital will then be responsible for ensuring that hearing screens are performed on all newborns prior to discharge. If an infant is not successfully screened prior to discharge, the birth hospital or birth center must so inform the parent or guardian, the infant's primary care physician and the Department, and must contact the Department-approved center to make an appointment for screening.

- If an infant does not pass a hearing screening, the hospital or birth center is responsible for notifying the parent or guardian, the primary care physician, and the Department of Public Health. The hospital or birth center is also responsible for scheduling a follow-up diagnostic appointment at a center approved by the Department of Public Health and providing the parent or guardian with the time and location of the appointment.

- Hospitals and birth centers are also required by the law to provide the Department of Public Health with their protocols for newborn hearing screening. The Department, in coordination with the Universal Newborn Hearing Screening Advisory Committee, will draft guidelines to assist hospitals and birth centers in the development of protocols. Prior to implementation a change to an approved protocol, a hospital or birth center must request and receive written approval of the change from the Department.

The draft amendments to the hospital and birth center licensure regulations have been released for a public hearing and comment period. The hearing is scheduled for June 1, 1999 and comments will be accepted through June 8, 1999. After review and consideration of all comments, the proposed amendments will return to the Public Health Council for final promulgation. Chairman Koh said in conclusion, "This is an example of early detection and prevention at its very best and we are hoping that this will all turn out to protect children and hearing in the future."

NO VOTE/INFORMATION ONLY

INFORMATIONAL BRIEFING ON PROPOSED AMENDMENTS TO THE HOSPITAL-BASED ADULT CARDIAC CATHETERIZATION SERVICES LICENSURE REGULATIONS (105 CMR 130.000):

Dr. Paul Dreyer, Director, Division of Health Care Quality, accompanied by Ms. Nancy Murphy, Policy Analyst, Division of Health Care Quality, presented the informational briefing on the hospital-based adult cardiac catheterization services licensure regulations to the Council. The following information was provided:

- In July 1977, the Department implemented hospital licensure regulations for adult cardiac catheterization services. Since that time, the Department has received comments on the

volume requirements per site for physicians who perform catheterization procedures at more than one hospital. The current regulations at 105 CMR 940 (F)(4) require physicians to perform a total of at least 100 cardiac catheterizations procedures per year and a minimum of 50 procedures at each site. Under the regulations, if a physician performs 25-50 procedures at a single site, the Invasive Cardiac Services Advisory Committee (ICSAC) is to review the physician's performance. A hospital is not to allow physicians to perform fewer than 25 procedures at its facility.

- Since the promulgation of the 1997 regulations, physicians have commented that in most cases, the patient's insurance company determines where the procedures are performed. The physician's volume is distributed across a larger number of facilities, making it more difficult to meet the 50 procedures minimum. Therefore, a subcommittee of the ICSAC recommended a revision to the regulations that would allow physicians to perform between 25 and 50 procedures at multiple sites, as long as the physician performed 50 procedures at least one site. This site would be considered the physician's primary hospital. The director of the catheterization service would consult with the directors of the other catheterization services for which the physician performed procedures to ensure the quality of the procedures at each site. The amended regulations would still require the performance of a total of at least 100 procedures and a minimum of 25 procedures at each site. The subcommittee felt strongly that, for the purposes of quality of care, it is essential that physicians perform a minimum level of procedures at each facility in order to assure familiarity with the support staff and hospital operating procedures.

- It was the intent of the original regulations to include Electrophysiology Study (EPS) procedures, then considered a type of catheterization procedure, under the same volume requirements for multiple site operators. For clarity, specific language to include EPS within this volume requirement has been included in the proposed amendments.

After a public hearing is held, the proposed amendments will then return to the Council for final promulgation.

NO VOTE/INFORMATION ONLY

INFORMATIONAL MEMO REGARDING ADMENDMENTS TO 105 CMR 155.000, ENTITLED PATIENT AND RESIDENT ABUSE PREVENTION, REPORTING, INVESTIGATION, PENALTIES AND REGISTRY THAT AUTHORIZE THE DEPARTMENT TO INVESTIGATE SUSPECTED CASES OF ABUSE, NEGLECT, MISTREATMENT, AND THE MISAPPROPRIATION OF PATIENT AND RESIDENT PROPERTY BY HOME HEALTH WORKERS:

Ms. Jean Pontikas, Assistant Director, Division of Health Care Quality, presented the amendments to regulations 105 CMR 155.000 to the Council. She said in part, "…We're here today to inform you that the Department plans to release for public comment and hold a public hearing on amendments to 105 CMR 155.000, Patient and Resident Abuse Prevention, Reporting, Investigation, Penalties and Registry. These regulations have been developed with

the assistance of a patient abuse advisory committee that was convened by the Department last fall to implement Chapter 336 of the Acts of 1998, which amends Mass. General Law, Chapter 111, Section 72f through 721, commonly referred to as the Patient Abuse Statute. The regulations set forth standards for prevention, reporting and investigation of patient and resident abuse, neglect, mistreatment, the misappropriation of patient and resident property by individuals who are working in or employed by a home health agency, homemaker agency, hospice program or a long term care facility."

"In the way of background", Ms. Pontikas continued, "the Department's Patient Abuse Statute was originally enacted in 1980, and its provisions included mandatory reporting of suspected cases of abuse, neglect or mistreatment of residents in long term care facilities, investigation of such cases by the Department, responsibilities of the facilities to monitor and train personnel, and measures to ensure confidentiality of reporters and Department reports. With the passage of federal regulations, commonly referred to as the Nursing Home Reform Act in 1987 and its subsequent regulations, the Department became responsible for investigating cases of suspected misappropriation of resident property as well. The Department was also required to provide hearings for all nurse aides accused of resident abuse, neglect, mistreatment or misappropriation. The Department was required to establish and maintain a registry of all individuals who have passed a competency test to become certified as nurse aides. Nursing homes participating in Medicare/Medicaid programs are required to check the Registry and employ only nurse aides who are certified. The Department is also required to place on the Registry all valid findings of resident abuse made against nurse aides. Under this federal law, facilities are barred from employing any nurse aide with a valid abuse finding. The State Legislature's 1998 amendments to the State Statute, Chapter 111, made substantial changes to the original statute and provided for the following: expansion of the Department's authority over the investigation and reporting of suspected cases of abuse by individuals working for home health agencies, homemaker agencies and hospice programs, in addition to long term care, which was previously covered. It also expanded the types of individuals who were mandatory reporters of suspected patient abuse in facilities and in the home setting. It now includes home health aides, homemakers, hospice workers, as well as agency administrators . It also included a provision that requires the Department to investigate cases of misappropriation of patient property. The Department must establish and maintain a registry which contains the names of all individuals certified as nurse aides, and findings of patient or resident abuse made against those nurse aides, home health aides, or homemakers. The amended statute also includes a requirement to provide notice and a hearing to all nurse aides, home health aides and homemakers, who are accused of patient or resident abuse, and it provides for remedies such as the suspension, probation or a warning letter in lieu of a hearing for a nurse aide or home health aide. It includes a requirement that long term care facilities, home health agencies, homemaker agencies and hospice programs check the registry before hiring an employee to determine whether or not the individual has a valid finding of abuse. If so, the facility or agency is prohibited from hiring that individual during the time period that the remedy or suspension is in effect. The existing regulations promulgated pursuant to the original statute apply only to long term care facilities. Many of their provisions are inconsistent with the requirements of the federal law, as well as those of the newly amended state statute. Therefore, we have made extensive revisions and amendments to those regulations in order to incorporate the provisions of both the federal law and the new state statute. The

substantive changes to Department activities will be the addition of receiving reports and investigating abuse cases involving home health agencies, homemaker agencies and hospice programs, as well as maintaining the registry and holding hearings for home health aides and homemakers."

No Vote/Information Only

INFORMATIONAL BRIEFING ON PROPOSED AMENDMENT TO THE DETERMINATION OF NEED REGULATION 105 CMR 100.000 GOVERNING APPLICATIONS ELIGIBLE FOR DELEGATED REVIEW AND ACTION/INFORMATIONAL BRIEFING ON PROPOSED REVISIONS TO THE DETERMINATION OF NEED GUIDELINES FOR MEGAVOLTAGE RADIATION THERAPY SERVICES:

Ms. Joyce James, Director, Determination of Need Program, presented the proposed regulations and guidelines to the Council. Ms. James said, "The purpose of the memorandum is to inform members of the Public Health Council that the Department plans to release for public hearing amendments to the Determination of Need (DoN) regulations and also proposed revisions to the radiation therapy guidelines. The amendment to the regulations (105 CMR 100.000) allows radiation therapy applications for DoNs to be reviewed through the delegated review process. If adverse comments are filed or if the Commissioner decides not to approve a project, the application would be presented to the Public Health Council pursuant to 105 CMR 100.510. Docket item 5 is proposed changes to the radiation therapy guidelines and these changes allow existing radiation therapy services that are operating at or above a certain capacity to expand new services if they meet certain criteria."

Ms. James noted further, "Currently, existing megavoltage therapy units are operating at or above capacity resulting in treatment delays for patients. In order to provide timely access to services in facilities that currently offer radiation therapy, Staff is proposing to allow such services the option of adding new units if they can demonstrate that they are indeed operating at capacity. Need for additional radiation therapy capacity was used up at the April 27, 1999 Public Health Council meeting, when Council approved the application filed by Morton Hospital and Medical Center, Good Samaritan Medical Center and Saint Anne's Hospital to establish radiation therapy services on the campus of Morton Hospital. These changes apply only to the health care requirements section of the guidelines."

No Vote/Information Only

REQUEST FOR FINAL PROMULGATION OF AMENDMENTS TO REGULATIONS 105 CMR 120.000 ET SEQ.: THE MASSACHUSETTS REGULATIONS FOR THE CONTROL OF RADIATION (MRCR):

Mr. Robert Hallisey, Director, Radiation Control Program, said, "We are here today to seek final approval of amendments to the Massachusetts Regulations for the Control of Radiation – 105 CMR 120.000. The Public Health Council was given an informal briefing on these proposed amendments on October 28, 1998. A public hearing was held on November 24, 1998. We received comments from eight people. Revisions were made to the following four sections: Definitions (105 CMR 120.005); Radiation Safety Requirements for Industrial Radiographic Operations (105 CMR 120.300); X-rays in the Healing Arts (105 CMR 120.400); and Transportation of Radioactive Materials (105 CMR 120.770). An entirely new section was developed for Therapeutic Radiation Machines (105 CMR 120.430) and editorial corrections were made throughout the previous edition of the Massachusetts Regulations for the Control of Radiation (MRCR). The proposed amendments to 105 CMR 120.000 were drafted by using the Suggested State Regulations for the Control of Radiation (SSRCRs) as well as newly adopted Nuclear Regulatory Commission (NRC) regulations dealing with the transportation of radioactive materials."

Mr. Hallisey gave some background on the regulations. He stated, "The existing set of comprehensive regulations pertaining to the control and use of radioactive material and radiation in the Commonwealth was first drafted by the Radiation Control Program and promulgated on March 11, 1994, and February 24, 1995, by the Public Health Council. These regulations were subsequently revised by the Public Health Council on December 19, 1995. Both the regulations and the revisions to them were part of the process involved in having Massachusetts achieve Agreement State Status with the Nuclear Regulatory Commission (NRC). On March 21, 1997, Massachusetts became the 30th agreement state. As such, the Commonwealth assumed the authority and responsibility for regulating users of source, byproduct, and special nuclear materials. Prior to Massachusetts becoming an Agreement State, personnel from the NRC performed all licensing and inspection activity for the more than 500 licensees operating in the Commonwealth."

In conclusion, Mr. Hallisey stated, "These revisions to the MRCR will not be increasing Massachusetts licensees' regulatory requirements. The revisions are intended to unify, clarify and simplify the regulatory requirements for licensees and make our MRCR requirements consistent with NRC and other jurisdictions…We respectfully request that the Council approve the attached regulations."

After consideration, upon motion made and duly seconded, it was voted: (unanimously) to approve for promulgation **Amendments to Regulations 105 CMR 120.000 et seq.: The Massachusetts Regulations for the Control of Radiation (MRCR**); that a copy be forwarded to the Secretary of the Commonwealth; and that a copy be attached and made a part of this record as Exhibit Number 14,651.

COMPLIANCE MEMORANDUM: PREVIOUSLY APPROVED DoN PROJECT NO. 4-1290 OF LOGAN HEALTHCARE FACILITY, INC.:

Ms. Joyce James, Director, Determination of Need Program, presented the request by Logan Healthcare Facility to the Council. She noted, "…The holder is requesting an additional increase of $332,500 (May 1998 dollars) in construction costs, including: $71,500 for construction contract, $181,000 for site and soil investigation, and other costs of $80,000 for medical gases equipment required to treat higher acuity patients. Based on the documentation submitted by the holder, the additional construction contract cost is for the increase of 650 gsf, which is necessary to provide adequate general storage space and a full laundry for the 82-bed facility. The site and soil investigation cost is for ledge removal and additional excavation and backfill at the project site. During the site work construction phase, a significant amount of ledge was encountered which was not apparent during preliminary site and soil testing. The holder decided to purchase medical gases equipment instead leasing, as proposed in the initial application, because it was determined to be more cost efficient. The holder claims that these increases were legitimate costs, which were not anticipated at the time the application was filed. In reviewing the holder's request for the increase, staff has examined whether the requested additional costs were reasonable in light of past decisions, were not foreseeable at the time the application was filed and were beyond the holder's control. Consistent with the Council's past decisions, staff finds that the additional costs could not have been reasonably foreseen and were not reasonably within the control of the holder."

A brief discussion followed, whereby Dr. Sterne, Council Member said, "On July 1, 1998 the approval was conditional that the final cost figure unaccompanied by any further increases inflationary or otherwise. I note that the language looks similar this time around and I would make a suggestion that if, in fact, those are obligations that we are not going to hold parties to, that we strike that language from our final decisions, both previously and currently…I would ask the staff for any future language to consider altering it."

After consideration, upon motion made and duly seconded, it was voted: (Dr. Koh, Dr. Askinazi, Mr. Phelps, Mr. Sherman, Ms. Slemenda, and Mr. Sneider in favor; and Mr.George Jr. and Dr. Sterne opposed to approve the amendment to **Previously Approved Project Application No. 4-1290 of Logan Healthcare Facility, Inc.** to increase the maximum capital expenditure from $6,226,524 (May 1998 dollars) to $6,599,024 (May 1998 dollars) and modify a condition of approval based on staff recommendation. This amendment is subject to the following conditions:

1. The holder shall accept $6,599,024 (May 1998 dollars) as the final maximum capital expenditure associated with this project. No further increases, inflationary or otherwise, shall be approved.

2. All other conditions attached to the original and amended approval of this project shall remain in effect.

The MCE is itemized as follows:

Construction costs:

Land Acquisition	$557,780
Land Development	522,000
Construction Contract \	
Fixed Equipment not in Contract >	4,157,580
Architectural & Engineering Costs /	
Site Survey and Soil Investigation /	
Major Movable Equipment	256,222
Pre & Post-Planning & Development	49,270
Other: Medical Gases Equipment	80,000
Total Construction Costs	**$5,622,852**
Financing Costs:	
Net Interest Expense	431,513
Costs of Securing Financing	544,659
Total Financing Costs	**976,172**
Total MCE	**$6,599,024**

****

The meeting adjourned at 10:45 A.M.

_____

Howard K. Koh, M.D., M.P.H.
Chairman

LMH

MINUTES OF THE PUBLIC HEALTH COUNCIL

MEETING OF MAY 25, 1999

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH